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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,326	07/18/2003	Arnold Hoffman	HOFFMAN9	2518
1444	7590	02/17/2006	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			DELACROIX MUIRHE, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/621,326	Applicant(s) HOFFMAN ET AL.	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The following is responsive to applicant's remarks received Nov. 4, 2005.

Upon further consideration of the claims, the examiner respectfully submits the following supplemental restriction requirement.

Due to the complex nature of the claims, no request for an oral election is being made.

Please see MPEP 812.01.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a method of treating a tumor in a subject, by administering at least one agent which decreases the $[GSH]^2/[GSSG]$ ratio in malignant cells, classified in class 514, subclass 21+.
- II. Claims 5-16, drawn to a method of treating a tumor in a subject by administering a synergistic combination of agents that decrease $[GSH]^2/[GSSH]$ ratio in malignant cells, classified in class 514, subclass 21+.

The inventions are distinct, each from the other because of the following reasons:

The inventions described in Groups I and II are independent and distinct. The method in Group I involves treating a tumor in a subject by administering to the subject an effective amount of at least one agent that decreases the $[GSH]^2/[GSSG]$ ratio in malignant cells of the tumor, wherein the agent is administered for a period of time within the range of from about 15 to 75 hours. The method of Group II involves treating a tumor in a subject, however, the method requires administering a synergistic combination of at least two agents that decrease the $[GSH]^2/[GSSG]$ ratio in malignant cells of the tumor, wherein the at least two agents are selected

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from four classes of compounds. The method in Group I does not require the synergistic combination of the method of Group II. Thus, while the methods of Groups I and II achieve the same objective, i.e. treatment of a tumor by decreasing the $[GSH]^2/[GSSG]$ ratio in malignant cells of the tumor, they do so by employing different method steps. Moreover, the search required for the method of Group II would not be required for the method of Group I. For these reasons, the inventions of Groups I-II are considered to be independent and distinct, and restriction for examination purposes is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: For Group I, the species of compounds are described in claims 2 and 3. For Group II, SPECIES 1 (claim 6) comprises the synergistic combination containing an agent that oxidizes GSH (i) **and** an agent that forms an adduct or conjugate with GSH (ii); SPECIES 2 (claim 10); comprises the synergistic combination containing an agent that oxidizes GSH (i) **and** an agent that inhibits GCS enzyme (iii); SPECIES 3 (claim 12) comprises the synergistic combination containing an agent that oxidizes GSH (i) **and** an agent that inhibits the GR enzyme (iv); SPECIES 4 (claim 14) comprises the synergistic combination containing an agent that forms an adduct or conjugate with GSH (ii) **and** an agent that inhibits the GCS enzyme (iii); and SPECIES 5 (claim 15) comprises the synergistic combination containing an agent that forms an adduct or conjugate with GSH (ii) **and** an agent that inhibits the GR enzyme (iv). The patentably distinct species for item (i) in claim 5 are described in claims 7, 11 and 13; the patentably distinct species for item (ii) are described in claim 8; the patentably distinct species for items (iii) and (iv) are described in claim 7, 8, 11, 13.

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If Group I is elected, applicant must elect a single species of compound. If Group II is elected, Applicant must elect one of SPECIES 1-5 with a further election of a specific agent for items (i)-(iv).

Examination of the generic claims in Groups I and II in their entirety would constitute an undue burden on the Examiner. The distinct nature of the species above is supported by the fact that each compound has a different structure/chemistry. Such is sufficient to indicate that each compound and their combinations listed above are differently searched in the patent and non-patent literature and that a search for one compound will not necessarily result in a comprehensive search of any one or more of the other compounds listed. Despite the fact that applicant may have established an underlying commonality for the claimed compounds, it remains that each of the compounds and combination thereof are recognized in the art as being chemically and structurally distinct from one another and, thus, each of the above-identified species is capable of supporting separate patents.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 5 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

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limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

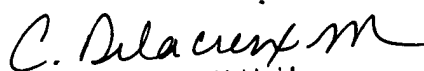
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybillie Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM 
Feb. 15, 2006


Cybille Delacroix-Muirheid
Patent Examiner Group 1600